

# RESEARCH PROTECTIONS UPDATE

*News and Comment on the Protection of Human Subjects and Animals in Navy Research*

*Volume 2, Number 1*

*humanresearch@us.med.navy.mil*

*January 2007*

## Comment

### **New HRPP Instruction Clarifies Command Responsibilities**

The Navy's newly approved policy for protection of human subjects, provided in SECNAVINST 3900.39D, highlights five critical areas of responsibility for commands that conduct research with human subjects: (a) maintaining an approved DoD Navy Assurance; (b) education and training of all personnel involved in human subject research; (c) designating an Institutional Review Board (IRB) to review research; (d) monitoring of research; and (e) ensuring effective communications among principal investigators, scientific reviewers, IRB members, and command staffs.

The instruction provides the foundation for the Navy's new HRPP policy. In coming months, Research Protections Update will explore in-depth key new directions defined in the new instruction.

Para. 6a(4) of the instruction highlights the responsibilities of commands, encompassing roles for all personnel involved in human subject research: "Commanders, Commanding Officers, Officers in Charge, heads of activities, scientific and technical program managers, project directors, IRB members, IRB support staff, and investigators shall maintain concern for the safety and welfare of volunteer subjects."

Para. 6a(4)(a) declares that "human subject research shall not be initiated until the institution holds a valid Assurance for the Protection of Human Research Subjects, the research protocol has been reviewed by an IRB, and approved by an appropriate research approval authority."

SECNAVINST 3900.39D defines an Assurance as a "document originated by the institution engaged in human subject research that states that it will comply with federal, DoD, and DON requirements for human subject protections."

It continues that "Key requirements of the DoD Navy Assurance are completion of research ethics training, designation of IRB(s) to review research protocols, and the institution's plan for monitoring human research." Commands are accountable for allocating resources adequate to ensure compliance with their Assurance (para. 8c(19)).

The requirement for education and training (para 6a(2)) stipulates that "all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing research ethics and human subject protections training appropriate to each individual's level of

involvement duties, and responsibilities."

The DON HRPP has developed a number of training modules that are accessible through the Collaborative Institutional Training Initiative (CITI) website ([www.citiprogram.org](http://www.citiprogram.org)). See Research Protections Update October 2006.

The instruction says (Para. 8e) that "the primary role of the IRB is to ensure the safety and welfare of human research subjects," adding that IRBs make recommendations to the approval authority for research protocols."

Compliance with HRPP policy requires commands to monitor research being conducted by observ-

*(Continued on page 2)*

#### **Also in this Issue:**

***DDR&E Report on DON  
HRPP***

***Pace Picks Up for Adden-  
dums***

***Animal Research Protection  
New, Renewed Assurances***

***Q&As: Focus on Training***

***Vet Director Honored***

DDR&E Report

## DON HRPP: “A New Message and Tone”

The Office of the Director of Defense Research and Engineering (DDR&E), in a late-December report on the Navy’s human research protection program, said that “the Navy has made significant improvements in their HRPP” since DDR&E’s approval of the Navy HRPP Management Plan in May 2005.

### *“High-Caliber Program, Highly Regarded”*

The report said that “Navy senior leadership is extremely committed to a high-caliber program that is highly regarded not only within the DoD, but also the non-federal organizations.”

The report, by the DDR&E BioSystems directorate, which oversees human research protections for the military services and DoD agencies, is based on DDR&E’s review of the DON HRPP carried out in June 2006.

In mid-June, BioSystems Director Dr. Robert Foster and Ms. Patty Decot, Assistant Director for Regulatory Affairs and International Programs, met with Surgeon General of the Navy Vice Adm. Donald C. Arthur, DON HRPP Director Capt. Eileen Villasante, and Dr. Tim Singer, then-Acting Director of the Research Protections Division at the Office of Naval Research (ONR). Singer became director of the division in August 2006. The DON HRPP program resides at the Navy’s Bureau of Medicine and Surgery (BUMED).

The December DDR&E report evaluated the DON HRPP’s progress in such areas as education and training; stability of policies and procedures; and initiatives for improvement of the program. Among many other

areas, it also looked at Navy recommendations for changes to the DoD Human Research Protections regulation, DoDD 3216.2, and at the implementation of policies and procedures since approval of the Navy’s HRPP Management Plan.

The report cited Navy recommendations for modifying DoDD 3216.2 to allow non-federal employees to serve as members of Institutional Review Boards (IRBs). DDR&E plans to discuss this recommendation and others with the DoD Coordinating Committee for Human Subject Research Protections.

The DDR&E report also discussed DON HRPP proposals for changes to DoDD 3216.2 regarding medical monitors, undue influence, and indemnification of research subjects from expenses incurred due to participation in any research, rather than only research that is greater than minimal risk.

### *New SECNAVINST*

A key element of the DON human research protection program is the approval by Secretary of the Navy Donald C. Winter of SECNAVINST 3900.39D. Secretary Winter signed the instruction on November 6, 2006. The new Navy program, DDR&E said, provides “clearer lines of authority from the institutions to BUMED and ONR,” and that “oversight from these two offices has been strengthened and harmonized.”

The report also discussed the role of the CNR, a two-star admiral, in overseeing research activities at three-star commands. It recognized the specific role of the

*(Continued on page 5)*

---

## New HRPP Instruction Clarifies Command Responsibilities

*(Continued from page 1)*

ing and/or meeting with investigators and auditing their research documents, such as approvals letters and copies of subjects’ consent forms.

Commands with IRBs must monitor their functioning and review their SOPs at least annually to ensure that they follow current guidance. Communication becomes a critical command responsibility. Commanders must establish methods for keeping personnel in-

involved in human subject research informed and up-to-date. IRBs must report suspensions or terminations of approved research, unanticipated problems, among others. Commanders, Commanding Officers, and Officers-in-Charge also must follow procedures to report suspensions or terminations of research, unanticipated problems and incidents of non-compliance, among others, to the DON HRPP.

FWA Addendums

## DON HRPP Steps Up Pace of Addendum Approvals

The Surgeon General of the Navy, acting on recommendations by the DON HRPP, approved eight Addendums to Federalwide Assurances (FWA) in November and December of 2006 to non-Navy “extramural” research performers, including some of the nation’s top universities, enabling them to start work on Navy-supported research involving human subjects in a wide range of science and technology areas.

In order to conduct research with human subjects, Naval commands are required to hold a DoD-Navy Assurance approved by the Surgeon General. Non-Navy extramural sites that hold an FWA may obtain an Addendum to the FWA that addresses additional Navy and DoD requirements for human subject research.

### **Institutions Receiving Addendums**

Arizona State University  
Carnegie Mellon University  
University of Central Florida  
Florida State University  
Boston University  
University of Pittsburgh  
Clemson University  
University of Illinois at Chicago

The extramural research sites that received Addendums all are funded through the Office of Naval Research (ONR), which sponsors much of the Navy’s research in combat casualty care and human-machine integration, as well as in weapon, sensor, communications, and command-and-control systems.

For the human subject research efforts planned at the institutions receiving Addendums, principal investigators (PIs) will design, develop, and test reconfigurable and deployable prototype systems, and examine the transfer of training from “virtual” to “real-world” environments for military operations in urban terrain.

In other ONR-funded extramural research efforts with human subjects, PIs expect to develop predictive models of human motion as a foundation for real-time kinematic tracking and recognition of human movement.

Other research funded by ONR involving human subjects will look at the effectiveness of learning asso-

ciated with manipulation of various features of a pedagogical agent used in educational software. Another research project will test an “expert performance approach” to development of expertise and professional skills, with the goal of identifying how best to acquire and train relevant skills.

A number of additional Addendums from extramural research performers are awaiting review and approval at the DON HRPP.

ONR’s Research Protections Division coordinates the handling of extramural performers’ Addendums for the SG’s review and approval. The addendum requires (a) documentation of approval from an Institutional Review Board (IRB); (b) an IRB-approved research protocol; (c) an IRB-approved informed consent document, when applicable; (d) an executive summary of planned research (one-half to one page in length); (e) proof of completed human research training (training certificate, institutional verification of training, etc.); and (f) a completed DoD Navy Addendum. If the research is determined to be greater than minimal risk, the documentation provided to ONR must include the name and contact information for a medical monitor.

Further information on the Addendum process is available on the DON HRPP web site at <http://navymedicine.med.navy.mil/humanresearch/> or on the ONR Research Protections Division website ([http://www.onr.navy.mil/sci\\_tech/34/343/](http://www.onr.navy.mil/sci_tech/34/343/)). Contact the DON HRPP at [humanresearch@us.med.navy.mil](mailto:humanresearch@us.med.navy.mil) or (202) 762-0262, or ONR at (703) 588-2902.



*The original Naval Observatory Dome, part of the BUMED campus, viewed from the DON HRPP office*

DON Animal Research Protection

## The Animal-Care Facility Inspection

By Col. Mark Gold

The most important part of any animal use program is the local Institutional Animal Care and Use Committee (IACUC). The IACUCs are bound by a basic set of requirements set out in the *Animal Welfare Act Regulations* (9 CFR) as well as by other guidelines of funding and oversight agencies. One of the key requirements of 9 CFR is that the animal-use programs of research sites be reviewed and their facilities inspected at least every six months. SECNAVINST 3900.38C, *The Care and Use of Animals in DoD Programs*, also requires periodic program reviews and facility inspections.

Each facility inspection / program review (FIPR) should follow a strict six-month cycle. DoD research sites are not inspected by the USDA, but animal research programs must ensure that they comply with 9 CFR. We should keep in mind that some facilities require several days to complete their FIPR.

*The most important part of any animal use program is the local Institutional Animal Care and Use Committee (IACUC).*

SECNAVINST 3900.38C requires each DoD facility to use Appendix D to the instruction—a checklist—to document IACUC findings and distinguish between minor and significant deficiencies (those that threaten the health or safety of the animals). Any additional means of documenting deficiencies or plans for correction are at the discretion of the individual facility; this often can be done with an easily updated computerized spreadsheet. In cases where the IACUC identifies deficiencies, facilities are required to provide a “... reasonable and specific plan and schedule with dates ...” for correcting each deficiency.

Once the IACUC drafts the FIPR report, a majority of the IACUC members must sign the document. Any IACUC member may provide a minority view or abstain from signing. Once a majority have signed, the document is forwarded to the Institutional Official

(IO). Under DoD guidance, we should ensure that non-affiliated members participate in the FIPRs to provide “community participation” in this essential IACUC review process.

The law requires that no fewer than two IACUC members conduct each FIPR; *ad hoc* consultants are acceptable supplements. Maximum participation helps bring as many “eyes” as possible to the process of examining facilities and programs. This is the one best chance for the IACUC to identify issues that need attention or deserve recognition. Additionally, it may be one of the few times in the year to secure critical resources for animal care and use programs that are under-funded or unfulfilled.

Once the IACUC identifies a deficiency it must stick to the plan for correction described in the FIPR report. Should the IACUC fail to do so, and the failure results in a “significant deficiency,” it must report the deficiency to the USDA, the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International (required by the SECNAVINST for DOD facilities), the Bureau of Medicine and Surgery (for DON facilities), and any other funding or assuring agencies (e.g., the NIH Office for Laboratory Animal Welfare). The IACUCs must ensure that their plans are reasonable in terms of scope and schedule to produce the most successful outcome.

The IACUC, not the assigned veterinarian, performs the FIPR. The IACUC also completes the FIPR report and prescribes a plan for corrections. The veterinarian, while perhaps responsible for resolving individual deficiencies identified by the IACUC, is unlikely to be the sole “fixer” of FIPR deficiencies. Animal oversight is a most sacred IACUC responsibility. The FIPR is one of the most important parts of carrying out that responsibility at each animal-care facility.

*Col. Mark Gold, USA, is Director of Veterinary Affairs in the Office of Research Protections at the Bureau of Medicine and Surgery.*



New Navy Assurance Holders**DON HRPP Renews Six Assurances; New Assurances Approved**

The DON HRPP has renewed Navy Assurances for research with human subjects at the Naval Medical Center, San Diego; Naval Medical Research Center Detachment (NMRCDD Lima, Peru); U.S. Naval Hospital, Naples; and Naval Hospital Corpus Christi, Tex.

The Space and Naval Warfare Systems Center San Diego and the Naval Experimental Diving Unit (NEDU), Panama City, Fla., also received renewals.

DON HRPP staff members have conducted site visits to NMRCDD Lima, the National Naval Medical Center, and NEDU.

DON HRPP also approved new Assurances for the First Marine Expeditionary Force, Camp Pendleton, Calif., and the Naval Air Force, U.S. Atlantic Fleet,

Norfolk, Va.



*Mr. Roberto Fernandez, entomologist at the Naval Medical Research Center Detachment, Lima Peru*

**DON HRPP: “A New Message and Tone”**

*(Continued from page 2)*

CNR, defined in the new SECNAVINST, as “providing support and expertise to the SG for human research protections at the Systems Commands, operational forces, training commands, and DON-supported extramural performing institutions.” The DDR&E report noted that the SG retains final authority for non-medical research.

**“A Model Process”**

The DDR&E report pointed out that the Navy program has developed many new forms to implement their HRPP process: a Navy Assurance; Addendum to the Federalwide Assurance; and Joint Research Review Agreement (JRRA). It said that the DON HRPP “has standardized the submittal and review processes of these documents,” and added that “these forms seem reasonable in the context of DoD’s overall implementation of HRPP policy and are being modified for DoD-wide use.”

DDR&E noted that DON HRPP requires all human subject research, including research determined to be exempt per 32 CFR 219.101(b) to go through headquarters-level review at either BUMED or ONR. The study said that “Navy has created a model process not only for criteria of what is to be reviewed, but also for

standardizing the review procedures.”

The DDR&E report observed that BUMED and ONR “are successfully working with small institutions (small in number of annual protocols) to partner them with larger institutions that have robust IRB[s].”

**“Well-Established in the Medical Community”**

Commenting on Navy efforts to comply with DoD HRPP training requirements, the DDR&E report said that the DON HRPP has developed training modules, residing on the Collaborative Institutional Training Initiative (CITI) website, for Navy HRPP personnel, including researchers, IRB members, and commanding officers.

The report concluded that “Vice Adm. Arthur recognizes that the Navy HRPP is well-established in the medical community and attention is needed in the remainder of the Navy research portfolio to ensure policies are complied with.”

DDR&E added that “The Navy is beginning to establish a new message and tone—one of working with the institutions to establish a positive and collaborative relationship, to strengthen the quality of the HRPP at the foundation, and to tailor the HRPP to the institution.”

HRPP Questions and Answers

## HRPP Training: Biomedical or Social-Behavioral?

**Why are there different tracks for biomedical (BIO) and social-behavioral research (SBR) on the DON HRPP training program [the DON HRPP online training provided on the Collaborative Institutional Training Initiative (CITI) website, [www.citiprogram.org](http://www.citiprogram.org)]?**

The dual tracks of the DON HRPP training program reflect differing definitions, practices, and regulatory concerns of SBR and clinical research. Although the human subjects protection course structure divides the course into SBR and BIO, the DON HRPP has devised “learner groups” that blend both SBR and biomedical content.

For example, if you select the “Investigators and Key Research Personnel–Biomedical” learner group, your “Grade Book” generates a list of required modules, including “SBR for Biomedical Researchers” and “Privacy and Confidentiality–SBR.”

Researchers and IRB members whose focus includes both types of research should select the appropriate learner group under the BIO track. Personnel involved only in SBR with human subjects may select the appropriate learner group in the SBR track. All modules not included in the required portion of your Grade Book are available to you for information or continu-

ing education. Future DON HRPP modules will address unique Navy and DoD requirements.

**Which type of learner group should I select on CITI, Biomedical or Social-Behavioral?**

It depends on what you study, and how you study it. For example, biomedical protocols often include elements of SBR, which is why we include SBR content in BIO training modules. Vaccine research and diving research study the body’s response to physical stimuli and have a biomedical focus, whereas human factors and human cognition research tend to emphasize social-behavioral questions and measurements. Combat-related stress is a good example of a research area that may be studied from either perspective or both.

**I’m an investigator, but I’m also on the IRB. Which learner group should I select?**

The IRB member track. It’s more comprehensive. In order to advise commanding officers and Institutional Signatory Officials effectively, IRB members need information and understanding to apply ethical principles and regulatory requirements when reviewing research protocols.

---

Director of Veterinary Affairs Honored

## Director of Veterinary Affairs, Col. Gold, Honored

Col. Mark Gold USA, Director of Veterinary Affairs in the Office of Research Protections at the Bureau of Medicine and Surgery, was inducted into the Order of Military Medical Merit at the Annual Veterinary Services Holiday Ball on December 16.

Throughout his career Col. Gold has advanced the Army Medical Department’s biomedical research programs with unique contributions as a researcher, instructor, and veterinarian.

Col. Gold has served as Animal Use consultant to the Air Force and Navy Surgeons General, providing expert advice on USAF and USN animal-based research, development, training, and education programs.



*Col. Gold (right) with Brig. Gen. Michael Cates, Chief of the Army Veterinary Corps, at the OMMM induction ceremony.*

---